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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,449	11/30/2001	Shamim M. Malik	050623.00134	3441

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,449	MALIK ET AL.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,8-10,13 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,8-10,13 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 May 2009 has been entered. Claims 2, 3, 7, 11, 12, and 14-30 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A single claim which claims both an apparatus (a stent having a plasma-polymerized polymer film layer) and the method steps of making the apparatus (wherein the plasma-polymerized polymer film is formed by exposing the stent to an acrylic acid plasma) is indefinite under 35 U.S.C. 112, second paragraph. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101, which is drafted so as to set forth the statutory classes of invention in the alternative only. See MPEP 2173.05(p).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-6, 8-10, 13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Patent No. 6,083,257 - cited on 892 dated 6/6/08), Ecer et al. (U.S. Patent No. 4,486,247 - cited on 892 dated 6/6/08), Narayanan et al. (U.S. Patent No. 5,336,518), and Kraus et al. (U.S. Patent No. 6,712,846 B1).

Taylor discloses a stent (see entire document) comprising a radially expandable metallic stent body formed of a stainless steel alloy (for example, see column 5, lines 51-56 and lines 62- 63) having a polymer film in intimate contact with the tissue contacting surface of the stent (for example see column 3, lines 63-67). Taylor fails to disclose the stent body comprises a carbon deposit.

Ecer discloses a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material at a depth from about 300 to about 2500 angstroms, or of about 300 to about 1000 angstroms below the steel surface, which falls within the claimed range (for example, see column 1, lines 50-54 and 60-64). Ecer suggests that carbon is a known material for increasing the hardness of steel (for example, see column 1, lines 14-18). It is well known in the art that stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the performance of the stent within, for example, a pulsating lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's stainless steel stent body with a carbon deposit as taught by Ecer in order to provide the stent with the advantages described above.

Taylor discloses the polymer film is applied to the stent surface by dipping methods, thus Taylor as modified by Ecer fails to disclose the polymer film layer is “chemically” bonded to the carbon deposit. Kraus discloses a polymer coated metallic stent (see entire document). Kraus teaches the polymer may be applied to the metallic stent by chemical vapor deposition (for example, see column 5, lines 39-41 and claim

27), thus chemically bonding the polymer film to the metallic stent. Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Kraus to the metallic stent of Taylor as modified by Ecer would have yielded predicable results and resulted in an improved system, namely, a metallic stent with a carbon deposit having a polymer film chemically bonded thereto (i.e., to the stent including materials within the stent body such as the carbon deposit), thus reducing the risk of the film inadvertently coming off of the stent during handling and/or deployment.

Taylor also fails to disclose the polymer film is plasma polymerized. Narayanan discloses a metallic stent comprising a polymer film (see entire document). Narayanan teaches plasma polymerized films, such as HFBMA (which is an acrylate), to enhance metallic surfaces with permanent improved biocompatibility. Narayanan also teaches bioactive agents (or “therapeutic substance”; see claim 10 of the current application) formed on the plasma polymerized polymer film (for example, see column 3, lines 44-56), wherein the plasma-polymerized polymer film also provides a stronger bond with the bioactive agents, since covalent linkages are formed between the film and the agents (for example, see column 3, lines 34-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form a therapeutic substance on Taylor’s film layer as taught by Narayanan in order to enhance treatment and promote healing at the treatment site. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a plasma polymerized polymer film in Taylor's invention as taught by Narayanan in order to provide the advantages described above. With further respect to claim 4, it would have

been obvious to one having ordinary skill in the art at the time the invention was made to provide a film layer comprising an acrylate material as taught by Narayanan, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. With further respect to claim 6, Narayanan discloses the activated acrylate may comprise functional groups such as carboxy or amine (for example, see column 3, line 43 and 62-63).

For examination purposes, claim 5 is being treated as a product by process limitation, in that "the plasma-polymerized polymer film is formed by exposing the stent to an acrylic acid plasma" refers to the process of forming the plasma-polymerized polymer film and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a plasma-polymerized polymer film formed by exposing the stent to an acrylic plasma is directed to the method of making the polymer film and not to the final product made. It appears that the product disclosed by Taylor as modified by Ecer, Kraus, and Narayanan would be the same, especially since both

applicant's product and the prior art product have the same final structure of a metallic stent having a plasma-polymerized polymer film layer.

Response to Arguments

Applicant's arguments with respect to the limitation "the plasma polymerized film layer is chemically bonded to the carbon deposit" and the Kamath et al. reference have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 13 May 2009 with respect to the Ecer reference have been fully considered but they are not persuasive. The applicant argues that Ecer fails to teach the carbon is deposited at a depth of not more than about 2000 angstroms beneath the surface of the stainless steel. However, it is the examiner's position that Ecer discloses such an embodiment (at a depth from about 300 to about 2500 angstroms, or of about 300 to about 1000 angstroms below the steel surface, which falls within the claimed range; for example, see column 1, lines 50-54 and 60-64).

The applicant further argues that the combination of Taylor and Ecer is improper. The applicant states that Ecer addresses solely the problem of friction and wear resistance, and the wear of Taylor's stent surface would not be an issue since Taylor's stent is entirely coated with a polymer layer. However, Ecer also addresses the problem of hardness and teaches that carbon is a known material for increasing the hardness of steel (for example, see column 1, lines 14-18). It is well known in the art that stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the

performance of the stent within, for example, a pulsating lumen. Therefore, it is the examiner's position that the combination of Taylor and Ecer is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Examiner, Art Unit 3773
June 18, 2009